Vacuum Erection Devices to Treat Erectile Dysfunction and Early Penile Rehabilitation Following Radical Prostatectomy

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Current Urology Reports 2008, **9:**506–513
Current Medicine Group LLC ISSN 1527-2737

Vacuum erection devices (VED) are becoming first-line therapies for erectile dysfunction and preservation (rehabilitation) of erectile function following treatment for prostate cancer. Currently, phosphodiesterase-5 inhibitors have limited efficacy in elderly patients or patients with moderate to severe diabetes, hypertension, and coronary artery disease. Alternative therapies, such as VED, have emerged as a primary option for patients refractory to oral therapy. VED has also been successfully used in combination treatment with oral therapy and penile injections. More recently, there has been interest in the use of VED in early intervention protocols to encourage corporeal rehabilitation and prevention of post–radical prostatectomy venoocclusive dysfunction. This is evident by the preservation of penile length and girth seen with the early use of the VED following radical prostatectomy. There are ongoing studies to help preserve penile length and girth with early use of VED following prostate brachytherapy and external beam radiation for prostate cancer. Recently, there has also been interest in VED to help maintain penile length following surgical correction of Peyronie's disease and to increase penile size before implantation of the penile prosthesis.

Introduction

Erectile dysfunction (ED) is a common problem in men that has separate or overlapping organic and psychological etiologies. ED can arise after surgical intervention, such as radical prostatectomy for the treatment of prostate cancer, or following direct trauma or injury to the genital area [1,2]. It is a common complication of diabetes, occurring due to autonomic neuropathy, vascular insufficiency, or various psychological factors in at least 50% of men with diabetes who are older than age 50 [3]. ED may also exist in the 4% of the male population with physical disability, such as a consequence of spinal cord injury or damage to other nonsexual organs in the body (eg, following chemotherapy) [2]. ED also occurs as a result of cardiovascular disease, hypertension, hypercholesterolemia, smoking, and the abuse of drugs including alcohol [4].

Several means of treating ED are currently available, including the most commonly used oral phosphodiesterase-5 inhibitors (PDE-5). Other treatments include intracavernosal injection therapy and surgically implanted penile prostheses. Noninvasive drug-free solutions such as vacuum erection devices (VED) remain popular despite the recent introduction of oral therapies [5].

Oral PDE-5 therapies are currently the most popular initial choice for patients with ED. VEDs have become a popular second choice in the event of problems with a PDE-5, such as contraindications or significant side effects. In moderate and severe ED, most patients find little or no success with PDE-5 inhibitors. As a result, VED is being recognized as a valuable and effective first-line treatment option in a wide variety of patient types. More recently, the role of VED has expanded; it is now used as a combination therapy with PDE-5 inhibitors, in penile rehabilitation following radical prostatectomy and radiation therapy, and as an adjuvant therapy before penile implant surgery and graft repair for Peyronie's disease.

VED is a noninvasive, cost-effective form of drug-free therapy for patients suffering from ED. Some benefits are a high long-term compliance rate, increased spontaneity, and its noninvasive application. VED efficacy and safety have been well documented and rated highest among all ED treatment options in both categories.

The device can last 5 years or more and is therefore a long-term, cost-effective treatment for ED. The VED is

Figure 1. Vacuum erection pump, constriction rings, and case with DVD instructions. (*Used with permission from* TIMM Medical Technologies [Eden Prairie, MN].)

Figure 2. SurErec constriction ring (TIMM Medical Technologies, Eden Prairie, MN). The SurErec ring ensures that scrotal tissue is not drawn into the cylinder of the pump, giving many patients a more comfortable fit. (*Used with permission from* TIMM Medical Technologies.)

Table 1. Efficacy of vacuum erection device as primary treatment for erectile dysfunction

Study	Successful intercourse, % *(n)*
Nadig et al. [51]	91 (35)
Sidi and Lewis [9]	93 (26)
Vrijhof et al. [10]	72 (47)
Bosshardt et al. [11]	100 (26)
Baltaci et al. [12]	67 (49)
Gontero and Kirby [52]	52 (94)
Zippe et al. [14]	80 (74)
Lewis and Witherington [13]	83.5% (5847)

the standard option and the most commonly prescribed form of treatment for ED [6,7]. The VED is easy to use and after repeated use, a man can produce an erection in 2–3 minutes, thereby increasing spontaneity and patient compliance. Vacuum therapy generally takes the form of a tube, or cylinder, which is placed over the penis and then a vacuum is applied to promote an increase in penile blood flow due to negative pressure (Fig. 1). More recently, we have advised patients to use a SurErec ring (TIMM Medical Technologies, Eden Prairie, MN) that is preplaced at the base of the penis before using a VED pump. The SurErec ring is an ideal alternative for many men who find the standard tension ring too loose. For users who find it uncomfortable to slip the ring off the cylinder and onto the penis, the SurErec ring eliminates the transfer process, thus increasing compliance (Fig. 2). Once an erection is attained, a constriction ring should not be kept on for more than 30 minutes to prevent ischemia [8].

VEDs are drug-free, with limited side effects, yet some drawbacks to the system are instability at the base of the penis leading to unnatural pivoting, a bluish or cyanotic aspect, and a cool erection due to the constriction of the blood flow [9]. VED use is contraindicated in patients with blood dyscrasias, sickle cell, or blood disorders. Anticoagulants are not a contraindication to use the vacuum, but patients should be trained on how to avoid possible side effects, such as ecchymoses, skin edema, and abrasions [8].

VED as First-Line Therapy

Published clinical trials have firmly established the efficacy of VED as a first-line therapy (Table 1). In 1992, Sidi and Lewis [9] reported a 93% patient success rate (erection satisfactory for intercourse). In 1994, Vrijhof et al. [10] found a 72% patient success rate (successful intercourse) in patients with mixed etiologies. In 1995, Bosshardt et al. [11] showed a 100% patient success rate (80% rigidity or better). Also in 1995, Baltaci et al. [12] indicated a 67% patient success rate (overall effective-

Table 2. Efficacy and compliance of first-line treatment for erectile dysfunction

Treatment	Successful intercourse, %	Withdrawal from treatment, %	Reported adverse events
Oral therapy [53]			
Sildenafil	65	8	Headache
Tadalafil	62	13	
Vardenafil	59	20	
Intracavernosal injection			
Papaverine	53 [54]	40 [19,20]	Priapism, intracavernosal fibrosis, injection site pain, scar formation
Phentolamine + papaverine	68 [54]		
Alprostadil	72.6 [54]		
Polyagent: alprostadil, papaverine + phentolamine	91.6 [54]		
Penile implants [55]	83–85	86.2–93.6	NR
Surgical therapy [56]			
Vascular surgery	30	NR	NR
Vacuum erection devices	Up to 93 [9]	20 [15] to 54 [17]	Bruising, pain, obstructed ejaculation

NR—not reported.

ness). In 1997, Lewis et al. [13] found a 90% patient success rate (erection satisfactory for intercourse). In 2006, Zippe et al. [14] showed, in a randomized prospective study with 109 patients, an 80% patient success rate (sexual intercourse) in patients following nerve-sparing radical prostatecomy (NSRP).

Although success rates are high, some initial problems with vacuum therapy exist. In 1991, Turner et al. [15] showed a patient discontinuation rate of 20% in the first 12 months. In 1992, Van Thillo et al. [16] reported a 10% discontinuation rate. In 1993, Meuleman et al. [17] indicated a much higher dropout rate of 54% in the first month of use. In 1999, Derouet et al. [18] found that 20% of patients rejected vacuum therapy immediately, 30.9% discontinued use after 4 months, and another 7.3% discontinued use after 10.5 months. It is important to note that these figures compare favorably with available compliance data for intracavernosal injections that have shown dropout rates of up to 40%, with other studies documenting a 56% dropout rate within 1 year (Table 2) [19–21].

These high initial dropout rates provide a false impression of the effectiveness and patient-preference for VED, but in general, those who finally choose to use the device are happy to continue with it long-term. In 1992, Van Thillo et al. [16] found that of 30 men who tested a device, 66% continued using it for at least 6 months. In 2000, Nunez et al. [22] found 65 of 79 (82%) users surveyed used a VED for a mean of 34.6 months [22]. In 1999, Derouet et al. [18] found 41.8% of patients were long-term VED users (7–70 mo) and 69.8% of users never had problems with the device.

The common reasons for discontinuation are well known. They include discomfort associated with the tension band, the cumbersome nature of the device, and a cool or cold erection. As with any treatment for ED, sufficient education and periodic follow-up are necessary to teach patients the most effective way to incorporate a VED into their ED treatment plan.

VED as Preferred First-Line Therapy in Selected Patient Types

VED has been a preferred first-line treatment for ED in select patients with neurogenic, psychiatric, and arteriogenic (coronary artery) etiologies. In 1996, Seckin et al. [23] reported on 32 patients with spinal injury in which neurogenic factors were contributing to ED, finding the VED to be a better initial treatment in 22 patients (69%). In a study by Aloui et al. [24] on the use of VED as alternative treatment for impotence, 14 neurogenic patients using a VED found significant improvement in sexual function. Similarly, in 1991, Turner et al. [15] found improvements with the use of a VED in psychiatric impotence with improved symptomology. In 1990, Turner et al. [25] tested 29 psychiatric patients, with all showing improved sexual functioning and reduced psychiatric symptomology with the use of a VED.

VED is often the treatment of preference in older men. In 1998, Finelli et al. [26] studied 89 men with ED with significant arteriogenic issues who were between ages 65 and 83. One of the more popular initial treatment choices was a VED (27.0%). Of those who chose oral therapy, significantly more (78%) dropped out of using it than of those who were using VED (29%), yet initial choices made by these older men did not differ from men with ED in general [26].

VED as Second-Line Therapy

PDE-5 inhibitors are the most common first choice for ED treatment [27,28]. PDE-5 inhibitors selectively inhibit cyclic guanosine monophosphate-specific PDE-5, which enhances the vasodilating effect of endogenous nitric oxide [4]. Certain patients may have contraindications to the use of PDE-5s such as those being treated with nitrates or nitrites [29]. Sildenafil has overall success rates for all etiologies of ED of 50%–80%; however, if PDE-5 treatments fail, a VED is a safe and effective second choice in certain patients [30]. In a study of patients who were using other agents or devices for ED who were offered sildenafil, the drug was statistically no more effective than VED or intracavernosal injection [31]. In addition, VED is as effective as other forms of second-line treatment (Table 3). Furthermore, in a study of patients who were effectively using a VED but who were switched to sildenafil, 33% who expressed a preference decided to return to use of the VED, with adverse side effects of sildenafil being the main reason for preferring a VED [32].

Other types of ED patients benefit from VED as a second-line therapy. In a retrospective study of VED users, 41.8% were long-term users who did not respond to intracavernosal pharmacotherapy [18]. In patients who had infections, erosion, pain or tissue necrosis with a penile implant, 91% of those who wanted to use it reported successful use of the VED [33].

Table 3. Efficacy and compliance of second-line treatments for ED following failure with PDE-5 inhibitors

Treatment	Efficacy, %	Withdrawal from treatment, %
Intracavernosal injection		
Alprostadil	88 [57]	NR
Polyagent: alprostadil, papaverine + phentolamine	92 [58]	
Penile implant	> 85 [59]	NR
Vacuum erection device	Up to 93 [9]	20 [8] to 54 [15]

ED—erectile dysfunction; NR—not reported; PDE-5—phosphodiesterase-5.

VED as Combination Therapy

VED is a valuable first-line therapy when used in combination with other forms of treatment. Oral therapy is not always optimal in terms of efficacy and rigidity and the use of a VED will often increase patient compliance and satisfaction.

Oral PDE-5 therapy can augment efficacy and compliance of VED treatment when the individual therapy is ineffective. In 2005, Raina at al. [6] reported that 77% patients had improved rigidity and sexual satisfaction with the combined usage of sildenafil and VED. Similarly, in 2004, Chen et al. [34] reported on a prospective study of men who were unsatisfied with a PDE-5 inhibitors or VED alone, a significant increase in the International Index of Erectile Function scores in the combination group than in the individual VED and sildenafil group ($P < 0.0001$). In the study, 100% of patients unhappy with either treatment alone were satisfied when using the combined treatments [34].

In 2006, Shamloul et al. [35] showed that in 100 men presenting with "honeymoon impotence" (the inability to perform sex in the early days of marriage), 26 had an organic basis to their ED, and of these 22 were successfully treated with sildenafil combined with either a VED or self-injection.

In 2003, Wylie et al. [36] also demonstrated that combining VED with psychotherapy was effective in 45 patients with psychogenic ED who were offered psychotherapy; half were randomly assigned to receive a VED. Some improvement after the initial psychotherapy was reported by 84%, compared with 60% of those who did not use a VED. These patients provided an early demonstration of the capacity and potential benefits of physical intervention combined with psychotherapy, which can improve initial and ongoing response to sex therapy and may lead to a greater beneficial response than psychotherapy alone [36].

In 1997, Soderdahl et al. [37] in a trial originally based on the observation by a patient that a VED in combination with a penile prosthesis produced a more effective erection than prosthesis alone, all participants reported increased rigidity and patient–partner satisfaction. In 2005, Israilov et al. [38] reported on a study evaluating the effectiveness of a progressive program in ED patients with diabetes. Of those who were nonresponders or not eligible for oral treatment or who dropped out due to adverse effects, 9 of 13 (69.2%) responded to self-injection plus VED. Similarly, in 1998, Marmar et al. [39] reported a total of 21 of 22 men with partial tumescence following intracavernosal injection responded to a VED within 30–60 seconds and achieved a rigid erection.

VED as Adjuvant Therapy in Penile Rehabilitation After Radical Prostatectomy

VED plays a key role in the maintenance of length and girth, return to sexual activity, and recovery of erectile function following radical prostatectomy. A complication that patients often report following radical prostatectomy is shrinkage of the penis in both length and girth [40]. In 2001 pilot study, Munding et al. [41] reported that 71% of men had a decrease in penile stretched length after radical prostatectomy and 48% had a significant decrease in length of 1 cm or more. Similarly, in 2003, Savoie et al. [42] reported a decrease in penile length in 68% of their patients after radical prostatectomy, with 19% having a decrease ≥ 15%.

Table 4. Penile size shortening following radical prostatecomy

Study	No VED, %	With VED, %	Follow-up, *mo*
Munding et al. [41]	71	NR	3
Savoie et al. [42]	68.3	NR	3
Zippe et al. [14,60•]	62.8	23	9
Köhler et al. [44•]	45.4	12	6
Dalkin [43]	NR	3.5	3
Monga et al. [61]	62	0.27	12

NR—not reported; VCD—vacuum erection device.

Recent results indicate that the VED may have a significant role in preventing this complication. A 2006 study by Zippe et al. [14] found that patients using VED therapy after NSRP had a much higher success rate in maintaining length and girth. Following surgery, patients were instructed to use a VED for 5 minutes every other day for at least 9 months. Of the 60 compliant men, only 14 (23%) reported a reduction in penile length and girth compared with 85% (12 of 14) of non-VED group. In addition, 22 of 35 (63%) of men who used no erectogenic aid at all also reported a reduction in penile length and girth at 9 months' follow-up. Finally, of the compliant patients, 80% reported a quicker return to sexual activity with use of the VED [14]. Recently, this study has been confirmed that early use of VED preserves penile length and girth. In 2007, Dalkin et al. [43] at the Society of Urologic Oncology presented an abstract demonstrating that early use of VED 10 minutes per daily session reduced the likelihood of penile shortening from 48% in historical control to 3.5% [43]. Similarly, in 2007, Köhler et al. [44•] reported that early use of VED preserved penile length. In their study, VED was used 1 month after prostatectomy for 10 min/d without constriction ring. They found that after 6 months only 12% using VED had a decrease in penile length in contrast to 46% in the non-VED group [44•]. These data demonstrate that regular and early use of the VED can aid in preventing such penile shrinkage (Table 4).

VED is also considered to be among the best first-line treatments in these cases, providing oxygenation to the erectile tissue. Complications with ED following radical prostatectomy can lead to cavernosal hypoxia, due to the lack of natural erections, and this can produce cavernosal fibrosis that may result in long-term ED [1]. Although PDE-5 inhibitors are a common first-line treatment for ED following NSRP, some studies have concluded they are not very effective. In 2001, McCullough et al. [45] found that sildenafil is not effective early in the recovery phase following surgery and only increases in efficacy as the nerves recover. Bosshardt et al. [11] discovered that blood drawn into the penis with a vacuum system was 58% arterial and 42% venous.

Based on these pilot results, a multicenter study at The Florida Hospital (Global Robotics Institute), Duke University, The Prostate Center in Austin, and The Cleveland Clinic are investigating the role of VED immediately following robotic radical prostatectomy. This study currently includes 500 patients with 9-month follow-up. Preliminary results show patient compliance at 90%, maintenance of length and girth in 80% of patients, and a faster return of erections sufficient for intercourse. Patients are instructed to produce multiple erections with vacuum therapy daily in a 10-minute session without the tension ring. Although preliminary results are encouraging, longer follow-up is necessary to validate the results.

VED as Adjuvant Therapy in Penile Rehabilitation After Prostate Brachytherapy

ED is an important complication and outcome measure following treatment for localized prostate cancer. As the mean age decreases with the diagnosis, younger men are now electing prostate brachytherapy as their treatment option and therefore reporting sexual outcomes becomes more important in decision-making. Our center recently completed a study on early PDE-5 inhibitors following prostate brachytherapy [46]. Our unpublished data suggest that the first 6 months after prostate brachytherapy is a very important period when fibrotic changes and penile atrophy may occur. In addition to using PDE-5 inhibitors, it may be a time to preserve penile length and girth. Unpublished data from our center suggest that a significant decrease in penile length and girth occurs in the first 6–12 months. Currently, there is ongoing research to use vacuum constriction devices to preserve length and girth measurements in addition to early PDE-5 inhibitors to help preserve erectile function and rigidity.

VED as Adjuvant Therapy After Graft Surgery for Peyronie's Disease

Management of ED following surgery for Peyronie's disease surgery has been a difficult problem for urologists. The definitive surgical management of Peyronie's disease leads to significant penile shortening. In 1999, Lue and Ahmed [47] reported on the role of daily penile stretching for those using VED for 30 minutes following circular venous grafting in four patients with Peyronie's disease. At 6 months, three patients gained two inches, and at 18 months, two patients gained three inches. In 2002, Colombo et al. [48] found that daily application of VED twice a day for 20 minutes for 3 months following saphenous graft surgery for Peyronie's disease resulted in lengthening of the erected penis in 13 of

the 16 patients (mean, 1.8). Currently, there are a few ongoing studies on the role of VED for the treatment of Peyronie's disease.

VED as an Adjuvant Therapy for Preinflatable Penile Prosthesis

Recently, there has been enthusiasm for using a VED pump 2–3 months before inflatable penile prosthesis implantation. Recent data indicate that the use of a VED pump in this interval allows for a longer cylinder placement at the time of the penile prosthetic surgery [49]. Sellers et al. [49] routinely used a VED protocol (10 min/d), showing that a 2–3-cm longer cylinder can be used following the use of VED for presurgical stretching. A randomized pilot study is also ongoing in select centers to evaluate the use of VED and its effect on penile length and girth measurements in corresponding cylinder size before penile implant. Because the primary dissatisfaction patients have with penile prosthesis is decreased erectile length and girth, these data are forthcoming and may lead to a new, exciting role for VED.

Conclusions

VED is an important treatment modality and is actually a better first-line treatment for ED than other treatments in certain circumstances. Although most often considered as a second-choice form of treatment compared with PDE-5 inhibitors, certain patient types (neurogenic, psychiatric, arteriogenic) are more likely to benefit from the first-line use of VED. Studies suggest that VED can assist in penile rehabilitation following radical prostatectomy and radiation and also prevent penile shrinkage in both length and girth in patients undergoing definite treatment for prostate cancer. Currently, the role of VED in penile rehabilitation following prostate brachytherapy and cryotherapy is being explored. Other patients in whom VED has proved most popular include the elderly, patients with suboptimal or adverse results from oral therapy, and patients with moderate or severe ED. The use of VED in combination with other forms of therapy (ie, injections, oral drugs, intraurethral alprostadil) also has a place in the first-line treatment of patients with ED.

A complete understanding of patient preferences will lead to better long-term use of any form of ED therapy. Factors such as spontaneity, naturalness, onset, and duration of action play a role in influencing choice. Providing patients with full information on the pros and cons of treatment options is important and the clinician needs to educate the patient to provide the best available treatment [27,28]. The appropriate initial choice of therapy is also essential because costs associated with changes related to successive treatment failures can be high [50]. In addition, partner involvement is often vital to the success of the treatment [29].

In the PDE-5 era of treatment for ED, VED is becoming recognized once again as having a primary role in early penile rehabilitation in many patient types, specifically those treated for prostate cancer. The ability of VEDs to facilitate penile rehabilitation and stimulate sexual intercourse, especially following radical prostate surgery and radiation therapy, is a unique strength for which it stands alone from other forms of treatment. Due to its excellent efficacy rates, combined with its ease of use, noninvasiveness, and cost-effectiveness, VED must be recognized as a front-line treatment of choice for ED.

Disclosures

No potential conflicts of interest relevant to this article were reported.

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